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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,677	12/21/2001	Ryan S. Westphal	D0187 NP	3323

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EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,677	WESTPHAL ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 13 and 21, drawn to a nucleic acid encoding an HBMYCNG channel, host cells and methods of making and using the nucleic acid, classified in class 531, subclass 23.1.

II. Claims 9 and 14, drawn to an antibody to the polypeptide of HBMYCNG, classified in class 434, subclass 130.1.

III. Claim 10, drawn to transgenic animal expressing HBMYCNG, classified in class 800, subclass 21.

IV. Claims 11-12, and 22 drawn to the polypeptide HBMYCNG, classified in class 530, subclass 350.

V. Claims 15-17, and 20 drawn to a method of identifying compounds that regulate HBMYCNG, classified in class 435, subclass 7.2.

VI. Claim 18, drawn to a method of treating by administration of a compound that increases expression of a HBMYCNG, classified in class 514, subclass 1.

VII. Claim 19, drawn to a pharmaceutical composition, classified in class 514, subclass 1.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute

patentably distinct inventions for the following reasons: Groups I-IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group IV can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group I, such as in gene therapy, or to make a transgenic as claimed in Group III, or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group II, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group II can be used to obtain the protein of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. Therefore a search and examination of the methods of groups I-IV together would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Inventions I-IV are related to invention V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method

can be used to identify compound that changes the expression or activity of an inward-rectifying potassium channel.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process of making can be used to identify a compound comprises a pharmaceutical composition that affects inward-rectifying potassium channels expression or activity.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Groups V and VI are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Invention group V is a method of identifying compounds that modulate activity and expression of the HBMYCNG channel, by contacting compounds with a cell and measuring channel expression or activity. Invention group VI is a method of treating ion-channel related disorders by administration of an effective amount to a subject. The methods have distinct steps and goals and are not required for each other. Therefore a search and examination of the methods of group V and group VI would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-IV and VII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The products of Groups I-IV can be used to for things other than to make or identify the pharmaceutical composition of Group VII. For instance, the nucleic acid of Group I can be used to in gene therapy, the transgenic animal of Group III can be used to identify drugs that affect the activity or expression of any other channel than HBMCNG, the polypeptide of group IV can be used to make the antibody of group II. Therefore a search and examination of the methods of group I-IV and group VII would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Inventions I-IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation and different effects. Group VI is a method of treating a disorder by administration of a compound that increases the expression of HBMYCNG channel and none of the products of Groups I-IV are disclosed as compounds that increase the expression of the channel nor can they be reasonably construed to do such.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of use is a simple method of treating an ion channel related disorder by administration, which can by performed with a compound that modulates sodium channels, such as lidocaine, as well.

In Re Ochiai

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
6/12/06

David Romeo
DAVID S. ROMEO
PRIMARY EXAMINER